Guidance for Industry and FDA Staff

RESOLVING SCIENTIFIC DISPUTES CONCERNING THE REGULATION OF MEDICAL DEVICES

An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel

Draft Guidance — Not for Implementation

This guidance document is being distributed for comment purposes only.

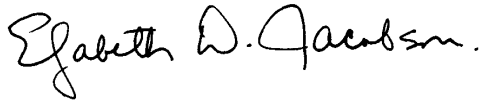
Draft released for comment on April 2 7 , 1999.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director

Foreword

The Food and Drug Administration Modernization Act of 1997 introduced many significant changes to the regulation of medical devices. As a result of these changes, FDA and the medical device industry should be better able to meet the public's need for innovative, safe, and effective health care products, and the U.S. device industry will be better able to compete in the global marketplace.

One of the provisions of the new law, section 404 on dispute resolution (new section 562 of the Federal Food, Drug, and Cosmetic Act), is designed to ensure FDA has effective processes to resolve scientific disputes that occasionally arise between FDA and the regulated industry. Fundamentally, the 1997 law directs FDA to use the independence and expertise of clinicians and scientists from outside FDA to advise the agency on issues where the industry and FDA professionals differ. Having a "dispute resolution panel" to which scientific disagreements and appeals can be brought and aired is a concept I wholeheartedly endorse. I also believe independent expertise will help ensure that, as regulators, we conduct our business as fairly and objectively as possible. This guidance provides the "ground rules" under which the Medical Devices Dispute Resolution Panel will function.



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Preface

This draft guidance document represents the Food and Drug Administration's current thinking on effective methods of resolving scientific disputes through use of the Medical Devices Dispute Resolution Panel of FDA's Medical Devices Advisory Committee. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Public Comment. Comments and suggestions regarding this draft guidance should be submitted by July 26, 1999 to—

Docket No. 99D-0239
Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Additional Copies. Additional copies of this guidance document and other related publications and information may be obtained through the CDRH Internet site (www.fda.gov/cdrh/resolvingdisputes/), or by fax from CDRH's Facts On Demand system at 800-899-0381 or 301-827-0111 (specify number 1121 when prompted for the document shelf number).

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RESOLVING SCIENTIFIC DISPUTES CONCERNING THE REGULATION OF MEDICAL DEVICES

A. Introduction

The Food and Drug Administration (FDA) and its Center for Devices and Radiological Health (CDRH) are constantly striving to improve the efficiency and effectiveness of our regulatory processes. One area that is receiving heightened attention is the need to ensure effective processes for resolving scientific disputes that arise between FDA and the medical device industry.

Presently, there is a wide array of mechanisms by which the device industry can obtain reconsideration of FDA decisions and actions[1], as provided for in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*), the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), and in regulations promulgated by FDA. The Food and Drug Administration Modernization Act of 1997 (FDAMA) has added to this array by directing FDA to ensure it has effective processes by which a medical device "sponsor, applicant, or manufacturer" can obtain independent review of a "scientific controversy" between that person and FDA.

To implement the new provision, FDA has amended 21 CFR § 10.75 to clarify the availability of review of scientific disputes by an advisory panel of experts when circumstances warrant. CDRH, in turn, has created a new advisory panel, the Medical Devices Dispute Resolution Panel, which will operate under FDA's Medical Devices Advisory Committee.

[1]These processes are summarized in *Medical Device Appeals and Complaints — Guidance on Dispute Resolution*, available from CDRH (see page ii for ordering information).

B. Purpose

In keeping with FDA's Good Guidance Practices policies and procedures[2], this document sets forth guidelines that will govern the operation of the Medical Devices Dispute Resolution Panel. Although it represents FDA's current thinking on the most effective methods to resolve scientific disputes concerning medical devices, this document is intended only to provide general guidance. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

In addition to serving as a useful forum in which scientific disputes in general can be aired, the Medical Devices Dispute Resolution Panel will implement four provisions of the Federal Food, Drug, and Cosmetic Act:

- **Section 514(b)(5)** requires the establishment of an advisory committee to take referrals of any matter involved in a proposed regulation which would establish, amend, or revoke a performance standard which requires the exercise of scientific judgment.

- **Section 515(g)(2)(B)** requires the establishment of an advisory committee to take referrals of petitions for review of —
    - the approval, denial, or withdrawal of approval or a premarket approval application, or
    - the revocation of an approved product development protocol (PDP), a declaration that an approved PDP has not been completed, or a revocation of an approved Notice of Completion that permitted marketing of a device developed under a PDP.

- **Section 522(b)** of the act[3] requires a process to resolve any disputes concerning the need for FDA to order a manufacturer to conduct postmarket surveillance for more than 36 months.

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[2]62 F.R. 8961 (February 27, 1997).

[3]This provision was added by § 212 of FDAMA.

- **Section 562** of the act[4] requires FDA to provide a procedure for review of all scientific disputes regarding the regulation of medical devices, including review by an appropriate scientific advisory panel, but only to the extent that other provisions of the act or FDA regulations do not already provide a right of review. FDA believes its current procedures already provide methods to obtain review of most, if not all, scientific disputes. The establishment of the Dispute Resolution Panel provides an additional, more focused, procedure for the timely review of scientific disputes.

This guidance shall not be applied to interfere with any statutory right to immediately request review of a matter pursuant to §§ 514(b)(5)(A)(ii), 515(g)(2)(A), 522(b), or 562 of the Food, Drug, and Cosmetic Act. A person who wishes to immediately invoke a right of review provided by one of these provisions should contact the CDRH Ombudsman.

C. Definitions

Authorized representative — an individual (*e.g.*, an attorney or a business or regulatory consultant) authorized by a medical device sponsor, applicant, or manufacturer to represent the individual's or entity's interests regarding a particular scientific dispute that is to be reviewed by the Medical Devices Dispute Resolution Panel.

CDRH Ombudsman — a person who is appointed by and reports directly to the Director, CDRH, and who serves as the primary mediator for a particular dispute involving regulated industry and the Center and also provides staff support for the Medical Devices Dispute Resolution Panel. If more than one dispute is under review at a particular time, the CDRH Director may appoint more than one ombudsman.

Market approval — a formal notification by FDA to an applicant, sponsor, or manufacturer stating that a medical device which is the subject of a premarket notification [510(k)], premarket approval application (PMA), or product development protocol (PDP) has been cleared or approved for commercial marketing.

Mediation agreement — a formal document reflecting resolution of a contested FDA decision or action between FDA and a requesting party.

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[4]This provision was added by § 404 of FDAMA.

Medical Devices Dispute Resolution Panel (also MDDRP) — the advisory panel that functions under the charter of the Food and Drug Administration's Medical Devices Advisory Committee, pursuant to §§ 514(b)(5), 515(g)(2)(B), 522(b), and 562 of the FD&C Act, to provide independent review of scientific disputes between FDA and medical device sponsors, applicants, or manufacturers.

Requesting party — a medical device sponsor, applicant, or manufacturer who has a scientific dispute with FDA and who requests a review of the matter by the Medical Devices Dispute Resolution Panel.

Scientific dispute (or scientific controversy) — a disagreement with a FDA science-based decision which bears on a regulatory matter pending before FDA or an appeal arising from a FDA science-based decision which served as the basis for a regulatory or public health decision or action rendered by FDA. This term *excludes* matters relating to potential criminal activity, allegations of intellectual or regulatory bias, and FDA's designation of a lead Center to regulate a combination product.

Statement of Findings — a written administrative record of the case review findings and recommendations by the Medical Devices Dispute Resolution Panel, which is transmitted to the CDRH Director for disposition.

D. Composition of the Dispute Resolution Panel

1. Membership. To facilitate the timely review of scientific disputes, and ensure that the scientific and clinical expertise of the Dispute Resolution Panel is appropriate to deal with each issue it reviews, the panel will be comprised of eight members: five standing members appointed to four-year terms, including a nonvoting member representing consumer interests and a nonvoting member representing industry interests, and three temporary voting members appointed to participate in the review of a specific dispute. One of the standing members shall be appointed by FDA to serve as the Chair. Standing members will have general scientific expertise applicable to a broad range of scientific issues (*e.g.*, a biostatistician or an epidemiologist). Temporary voting members will be chosen based on their experience, expertise, or analytical skills relevant to the review of a particular disputed issue. Temporary voting members will be drawn from —

(a) current members of other panels of the Medical Devices Advisory Committee,

(b) current special Government employees serving as consultants to the Medical Devices Advisory Committee or other FDA advisory panels or committees, and

(c) such other persons, recruited from the academic and private sectors or other appropriate organizations, as are appointed by the Commissioner as special Government employees to be consultants to the Medical Devices Dispute Resolution Panel.

Selection of temporary voting members will be subject to two restrictions. Temporary voting members will not be drawn from a Medical Devices Advisory Committee panel —

- that has had significant prior involvement with the particular issue in dispute; or
- where it is reasonably expected that the panel will be asked to render advice on essentially the same scientific dispute or application at a later date.

Notices requesting nominations for members of the Dispute Resolution Panel will be published in the *Federal Register* in accordance with 21 CFR §§ 14.82 and 14.84. In selecting panel members and consultants, FDA will emphasize diversity in scientific and health professional education, qualifications, training, and experience.

As special Government employees, Dispute Resolution Panel members will be subject to all applicable conflict-of-interest laws and regulations. Prior to final selection of members, potential conflicts-of-interest will be carefully scrutinized. If and when such conflicts are identified, nominees may be disqualified. If a conflict of interest is discovered after a candidate is selected and seated on the Dispute Resolution Panel, the member may be granted a waiver pursuant to Federal ethics rules, or be recused from the issue that may be affected by the member's conflict, or, if the conflict was deliberately concealed, may be dismissed from the Panel.

2. Term of Service. A standing member of the Dispute Resolution Panel will serve continuously for a single four-year term[5], unless extenuating circumstances allow or require a member to be

[5]In order to provide for the orderly recruitment and replacement of panel members, the initial appointments to the Dispute Resolution Panel will be as follows: one member will be appointed to a four-year term, one member will be appointed to a three-year term, and one member will be appointed to a two-year term. All subsequent appointments shall be for four-year terms, except (continued...)

excused, pursuant to 21 CFR 14.80 (e) and (f). A temporary voting member will serve for an indefinite term, ending when the CDRH Director takes final action on the matter.

E. How To File A Request For Review of A Scientific Dispute

1. Time frame for making a request. A party may request review of an FDA decision or action by the Dispute Resolution Panel by submitting a complete written request within 30 calendar days following the decision or action that is disputed.

2. Mailing address. The request for review and all subsequent correspondence should be addressed to:

CDRH Ombudsman (HFZ-5)
Office of the Center Director
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

3. Content. A request for Dispute Resolution Panel review should contain the following:

(a) The name, mailing address, and phone number of the requesting party, with an explanation of why the requesting party believes it has standing to request review by the Dispute Resolution Panel, and the name, mailing address, and phone number of the person who will serve as the contact point for the requesting party.

(b) A concise summary of the scientific issue in dispute, including a summary of the particular FDA action or decision to which the requesting party objects, any prior advisory panel action, and the results of all efforts that have been made to resolve the dispute. Although FDA will not apply an inflexible rule, ordinarily efforts to resolve the dispute through FDA's supervisory chain of command at least to the Office Director level will be considered a prerequisite to granting a request for review by the Dispute Resolution Panel.

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[5](...continued)
where the early resignation or removal of a panel member requires an appointment for the remaining period of that member's unfulfilled term.

(c) A clearly articulated summary of the arguments and relevant data and information. Material outside the official administrative record and not in the possession of FDA at the time the decision or action in dispute was made may be submitted only if it has a significant bearing on the issue or related public health considerations.

(d) A clear statement of the action requested of FDA.

4. Acknowledgment. The CDRH Ombudsman will provide a written acknowledgment to the requesting party, normally within five days of receiving a written request for review.

5. Effect of filing a request for review by the Dispute Resolution Panel. The filing of a request for, or FDA's granting of, a review of a matter by the Dispute Resolution Panel will not affect, delay, stay, or preclude any ongoing or future seizure, recall, suspension of marketing authority, or other regulatory action which FDA deems necessary to protect the public health.

6. FDA Referrals. FDA may at any time exercise discretion and refer a scientific dispute to the Dispute Resolution Panel for review, providing the following conditions are met:

(a) The scientific dispute involves FDA and a medical device sponsor, applicant, or manufacturer whose interests are or are likely to be adversely affected by an FDA decision or action.

(b) Reasonable efforts have been made by FDA to resolve the dispute through established processes, including review by the Center's supervisory chain of command (see 21 CFR § 10.75), and there is reason to believe that additional such review alone will not result in a resolution of the matter. At a minimum, the matter in dispute must normally have been reviewed at the Office Director level prior to referral to the Dispute Resolution Panel.

(c) The referral is consistent with the Preliminary Review criteria (page 9), and meets with the approval of the CDRH Deputy Director and the Panel Chair, as provided in the section on Initial Consultation With CDRH Officials and Panel Chair (page 10).

A referral by FDA is subject to the same requirements for public notice and notification of affected parties as a request from any other source.

7. Inquiries About the Process

Inquiries concerning how to obtain Dispute Resolution Panel review should be directed to the CDRH Ombudsman at 301-443-4690 (phone) or 301-594-1320 (fax). General information about the Dispute Resolution Panel, its procedures, and how to obtain review of disputed matters will be provided and regularly updated on the CDRH Internet site (at www.fda.gov/cdrh/resolvingdisputes).

8. Preliminary Review. Upon receipt of a complete request for Dispute Resolution Panel review, the CDRH Ombudsman will conduct a preliminary review of the request to determine whether:

(a) the request for review primarily concerns a scientific dispute or scientific controversy concerning an FDA decision or action;

(b) the request demonstrates sound scientific grounds supporting reconsideration and that relevant information or views contained in the administrative record were not adequately considered;

(c) the dispute is at an appropriate stage for independent review and the request has been submitted within 30 days of a disputed FDA action or decision;

(d) the request for review is submitted by a person with standing to bring the issue before FDA, that is, a medical device sponsor, applicant, or manufacturer;

(e) the FD&C Act and FDA regulations do not require use of a different method of review or appeal;

(f) the dispute does not involve:

(1) potential criminal activity (*e.g.*, data fraud, submission of false information, gratuities to FDA employees, unauthorized disclosure of proprietary information);

(2) allegations of intellectual or regulatory bias (including differential treatment) on the part of FDA employees, members of FDA advisory panels, or other special Government employees;

(3) regulatory jurisdiction (*i.e.*, which FDA component will have lead regulatory responsibility for a particular matter) or other matters in which regulatory policy or procedures are the dominant concerns; or

(4) a matter for which the CDRH Director has not been delegated authority;

(g) the matter in dispute is amenable to mediation or is sufficiently complex that specialized expertise and independent review by the Dispute Resolution Panel is warranted;

(h) reconsideration of FDA's decision or action is not outweighed by public health or other public interests;

(i) in the opinion of the CDRH Ombudsman, there is no alternative dispute resolution or appeals process that is clearly preferable; and

(j) the requestor has, when appropriate, made sufficient efforts to resolve the dispute through other, less formal dispute resolution mechanisms, particularly review through the supervisory chain as provided by 21 CFR § 10.75.

Examples of situations in which FDA expects to grant or deny requests for MDDRP review of scientific disputes are provided in Appendix B.

Upon completion of the preliminary review, the CDRH Ombudsman will take one of the following actions:

(1) Notify the requesting party that the request for review has been denied and provide an explanation of the reasons for denial. In appropriate cases, FDA will also inform the requesting party that it may re-submit the request if there is a reasonable probability that the request can be rehabilitated to overcome the deficiencies that caused the denial. FDA will also provide information on alternative dispute resolution or appeal processes.

(2) Ask for additional information necessary to make a determination.

(3) Proceed to consult with CDRH officials and the Dispute Resolution Panel Chair to make a determination as to whether mediation or Dispute Resolution Panel review is the most appropriate course, or whether some other dispute resolution process is preferable.

9. Consultation With CDRH Officials and Panel Chair. If, after completing the preliminary review, the CDRH Ombudsman determines that the threshold criteria have been met, the Ombudsman will consult the Panel Chair, and the appropriate CDRH Deputy Director, to make a determination as to whether mediation, Dispute Resolution Panel review, or some other dispute

resolution process is preferable. Once a determination has been made, the CDRH Ombudsman will notify the requesting party of FDA's decision to take one of the following actions:

(a) Offer mediation as an alternative or prerequisite to Dispute Resolution Panel review of the matter (for information on mediation, see p. 11).

(b) Grant the request for review by the Dispute Resolution Panel and, if feasible, specify when the proceeding will be convened. FDA will take into account the public health significance of a scientific dispute relative to other matters that may be pending before the Dispute Resolution Panel in determining when the particular matter will be heard by the Panel.

(c) Deny the request and provide information on alternative processes that can be used to resolve the matter in dispute.

FDA will make its decision within 30 days of receipt of the request unless unusual circumstances require a longer review period. Where unusual circumstances require more than 30 calendar days to make a decision, FDA will provide a written notice to the requesting party, and will include an estimate of when a decision should be expected.

10. Offer of Mediation as an alternative to Dispute Resolution Panel review. FDA may offer mediation as an alternative to a review by the Dispute Resolution Panel. An offer of mediation will define the scope of the proposed mediation. If an offer of mediation is made by the CDRH Ombudsman, the requesting party has 15 calendar days from the date of the notification to accept or refuse the offer. Any acceptance must be in writing. Failure to accept an offer of mediation within 15 working days will be treated as a rejection of the offer. FDA will then continue to consider the request for dispute resolution through independent review by the Dispute Resolution Panel.

If the requesting party accepts an offer for mediation, the CDRH Ombudsman, in the role of a neutral facilitator, shall initiate discussions as soon as practicable. In the event the CDRH Ombudsman is unable to act as mediator in a particular case, the Ombudsman will appoint a senior level CDRH employee to act as mediator.

The CDRH Ombudsman shall periodically inform the CDRH Deputy Director of the progress of ongoing mediation efforts. CDRH representatives engaged in mediation may periodically consult the CDRH Deputy Director for the purpose of obtaining the Deputy Director's views and guidance.

Should the parties engaged in mediation reach agreement, the CDRH Ombudsman shall document the outcome in a Mediation Agreement that reflects the resolution of the scientific dispute. The Agreement will be included in the official FDA case file. Copies of the Agreement will be provided to all parties involved in the mediation.

In accordance with sections 571(5) and 574 of the Administrative Dispute Resolution Act of 1990, as amended by the Administrative Dispute Resolution Act of 1996, P.L. 104-320, 5 U.S.C. §§ 571(5) and 574, all records of communications prepared for the purpose of mediation, including any memoranda, notes, or work products, excluding the Mediation Agreement, shall be confidential.

If, in the judgment of the CDRH Ombudsman, mediation efforts have failed to achieve satisfactory results within a reasonable time period (*e.g.*, 120 days), the Ombudsman may, upon written notice to the parties, terminate mediation.

At any time during mediation, the requesting party may:

(i) terminate mediation and withdraw the original request for Dispute Resolution Panel review; or

(ii) terminate mediation and request a decision on the original request for Dispute Resolution Panel review.

If mediation is terminated by a requesting party, FDA is under no obligation to grant the original request for Dispute Resolution Panel review.

11. Second Round Consultation With CDRH Officials and Panel Chair. If mediation fails, or if the requesting party reasserts its request for Dispute Resolution Panel review in lieu of mediation, the CDRH Ombudsman may confer again with the appropriate CDRH Deputy Director and the Dispute Resolution Panel Chair for the purpose of determining whether to proceed with a Panel review.

After making a determination to grant a request for Dispute Resolution Panel review, the CDRH Ombudsman will, in writing, inform the requesting party of the decision and the reasons therefor, and will provide a clear statement of issues to be considered by the Panel.

12. Scheduling of the Panel Meeting. Following acceptance of a request for Panel review, the CDRH Ombudsman shall:

(a) schedule a Panel meeting at such time as will ensure a full and timely hearing of the issues involved;

(b) at least 15 calendar days prior to a Panel meeting, as specified in 21 CFR § 14.20, publish a *Federal Register* notice announcing the date, time, and location of the meeting; to the extent consistent with protection of non-public information, the topics to be discussed; and inviting additional supporting materials that meet the criteria specified in section E (3);

(c) prepare a written summary of the matter in dispute, along with the arguments, relevant data and information submitted by the parties, for distribution to members of the Dispute Resolution Panel no later than 15 calendar days prior to the Panel meeting.

13. Denial of a Request for Dispute Resolution Panel Review. If the Center decides to deny a request for Dispute Resolution Panel review, the CDRH Ombudsman will, in writing, inform the requesting party of the decision and the reasons therefor, and will inform the requesting party of alternative avenues for reconsideration of the disputed matter, including an appeal of the denial to the FDA Ombudsman. If the Center denies a request for Dispute Resolution Panel review, the sponsor, applicant, or manufacturer will still be able to use any other available alternative means of resolving the dispute; see FDA's guidance, *Medical Device Appeals and Complaints — Guidance on Dispute Resolutions* (February 1998) for information on these alternatives (this guidance is available through the Internet at www.fda.gov/cdrh/modact/dispresl.pdf).

F. Panel Meeting Procedures

All meetings of the Dispute Resolution Panel will be governed by FDA regulations promulgated at 21 CFR Part 14. All Panel meetings will be open to the public as provided by the Federal Advisory Committee Act and FDA regulations except a portion of a meeting may be closed pursuant to 21 CFR § 14.27.

The requesting party will be accorded the right to speak first and present its views after which the FDA representative(s) and other affected and interested parties may address the Panel.

Each party may be accompanied by scientific experts, health professionals, legal counsel, and other technical specialists for the purpose of providing supplementary testimony or responding to questions by members of the Dispute Resolution Panel, pursuant to 21 CFR § 14.29.

During, and subsequent to, the presentations by both sides, members of the Dispute Resolution Panel may question the parties directly. No questioning by or debate between the parties will be permitted.

Every Panel meeting will offer at least a one hour open public hearing during which the Panel may hear arguments and receive information relevant to the matter that is the subject of the proceeding from the general public to the extent practicable.

Once deliberations have been completed, the Chair will determine if a consensus exists among Panel members and, if not, will call for a vote. The Chair shall not vote, except in the case of a tie vote, the Chair will cast the deciding vote.

FDA will provide for the transcription of all Panel meetings, and copies of transcripts will be available to the public pursuant to the Freedom of Information Act, 5 U.S.C. § 552, and FDA's Public Information regulations, 21 CFR Part 20.

Within 30 days of the Dispute Resolution Panel meeting the CDRH Ombudsman will prepare a written Statement of Findings summarizing the Dispute Resolution Panel recommendation, including any minority views. The Ombudsman will provide a copy of the Statement of Findings in draft form to the Panel Chair and to each Dispute Resolution Panel member who participated in the proceeding for review and will thereafter make such changes as are necessary to accurately reflect the Panel's review and recommendation. The Panel Chair will sign the final Statement of Findings and will forward it to the CDRH Director, through the appropriate CDRH Deputy Director, if necessary, for action.

G. FDA Action on Panel Findings and Notification of Decision

Upon receiving a Statement of Findings, the CDRH Director shall take one of the following actions, normally within 15 days:

(a) Uphold, modify or reverse the contested decision or action;

(b) Determine that additional information, evidence or deliberation is necessary and remand the matter back to the Dispute Resolution Panel with instructions for further consideration; or

(c) Conclude that a separate investigation is required by an appropriate FDA or other governmental investigative unit and make a referral.

Following a conclusion by the CDRH Director regarding the scientific dispute, the CDRH Ombudsman shall, in writing, notify the party, its authorized representatives and appropriate FDA officials of the decision by the CDRH Director, required action resulting from the decision, if any, and any rights of appeal that exist should the parties disagree with the decision.

The Statement of Findings, with the conclusion(s) of the CDRH Director, shall be made part of the official administrative record.

H. Appeal of Dispute Resolution Panel Findings/FDA Action

(1) FDA action on a Panel recommendation resulting from review under the provisions set forth in this guidance is not final FDA action for purposes of judicial review unless otherwise provided by statute or regulation.

(2) Any party who wishes to appeal a Dispute Resolution Panel proceeding or a final action by the Panel on procedural grounds should direct a written appeal to the CDRH Ombudsman. The Ombudsman will review the record of the particular proceeding, consulting with participants as necessary, and will recommend disposition.

(3) Any party who wishes to appeal a Dispute Resolution Panel proceeding on the basis of an alleged conflict-of-interest involving one or more Dispute Resolution Panel members should direct such appeal to the CDRH Advisory Panel Coordinator who, if warranted, will refer the matter to the appropriate FDA component for review and possible investigation.

I. Public Availability of Dispute Resolution Panel Records

As a matter of general practice, FDA will make publicly available all materials collected, prepared and presented to the Dispute Resolution Panel at the time of the Panel meeting, as provided by 21 CFR § 14.65 (c).

Following a meeting of the Dispute Resolution Panel, requests for materials, including a Statement of Findings and a written decision by the CDRH Director, must be made through the Freedom of Information Act process (see 21 CFR Part 20).

Timeline of a Review by the Dispute Resolution Panel

Filing a request for review — A complete request for a review by the Dispute Resolution Panel must be filed within 30 days of the FDA action or decision for which the review is sought.

FDA acknowledgment — FDA will provide written acknowledgment of a request for review within five days of receipt.

FDA preliminary review — FDA will normally complete its preliminary review within 30 days.

Response to an offer of mediation — If FDA makes an offer of mediation, it must be accepted within 15 days or it will be automatically withdrawn.

Mediation — Mediation should generally be completed within 90 days.

Dispute Resolution Panel meeting — FDA will attempt to schedule a Dispute Resolution Panel meeting within 60 days of its decision to assign an issue to the panel. FDA will publish a *Federal Register* Notice announcing the meeting at least 15 days prior to the meeting and will provide a summary of the matter in dispute to the parties and panel members at least 15 days prior to the meeting.

Preparation of a Statement of Findings — The CDRH Ombudsman will prepare a written Statement of Findings summarizing the recommendations of the Dispute Resolution Panel within 30 days of the panel meeting. The panel will approve the completed Statement within 15 days.

CDRH Director Decision — The CDRH Director will make a decision within 15 days of receiving the panel's Statement of Findings.

(All time frames are calculated on the basis of calendar days, and include holidays and weekends.)

References

1. Food and Drug Administration Modernization Act of 1997 (P.L. 105-115).

2. Federal Advisory Committee Act (5 U.S.C. App. II).

3. Administrative Dispute Resolution Act of 1996 (5 U.S.C. 571-584).

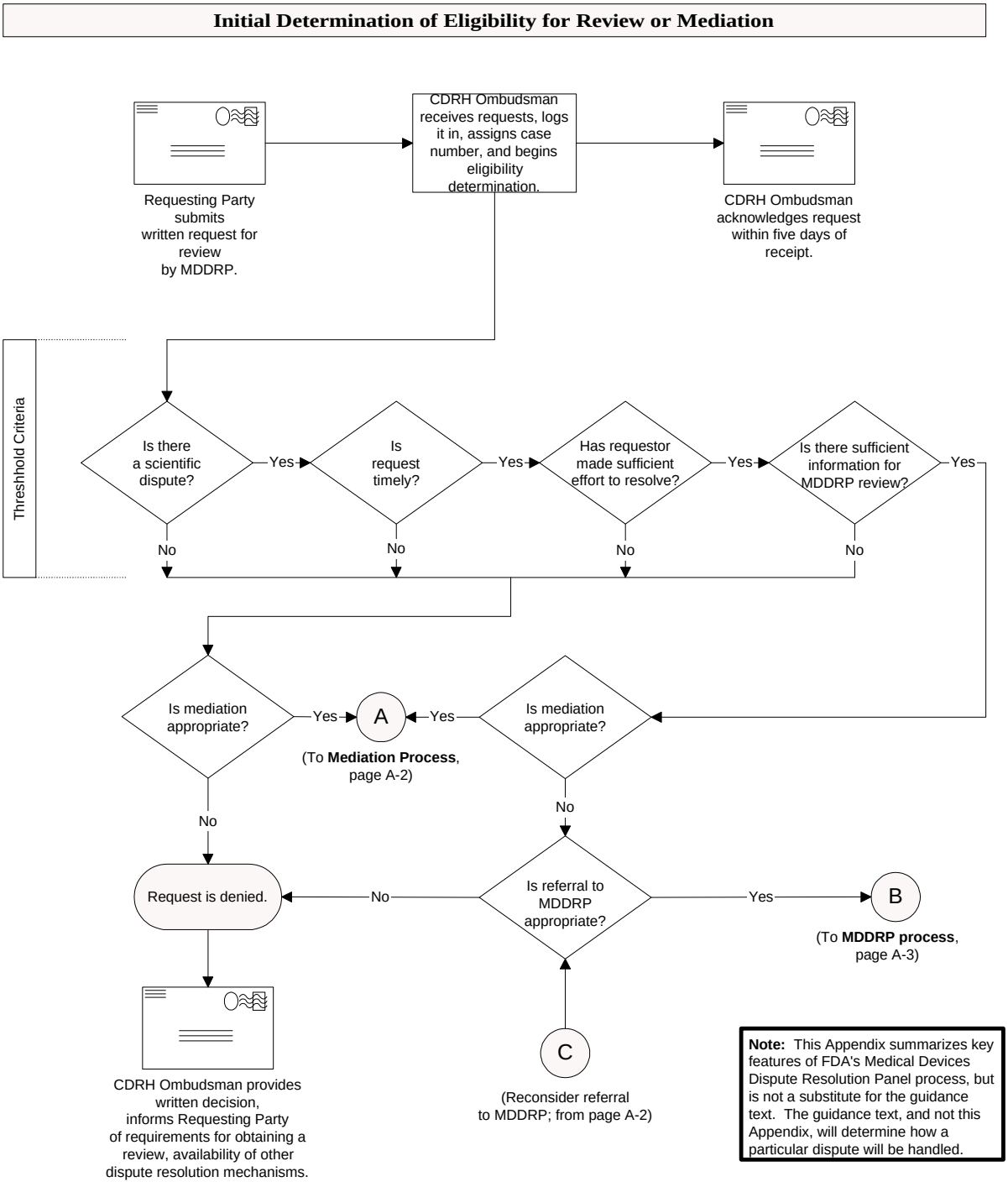
4. 21 CFR Part 14 — Public Hearing Before A Public Advisory Committee.

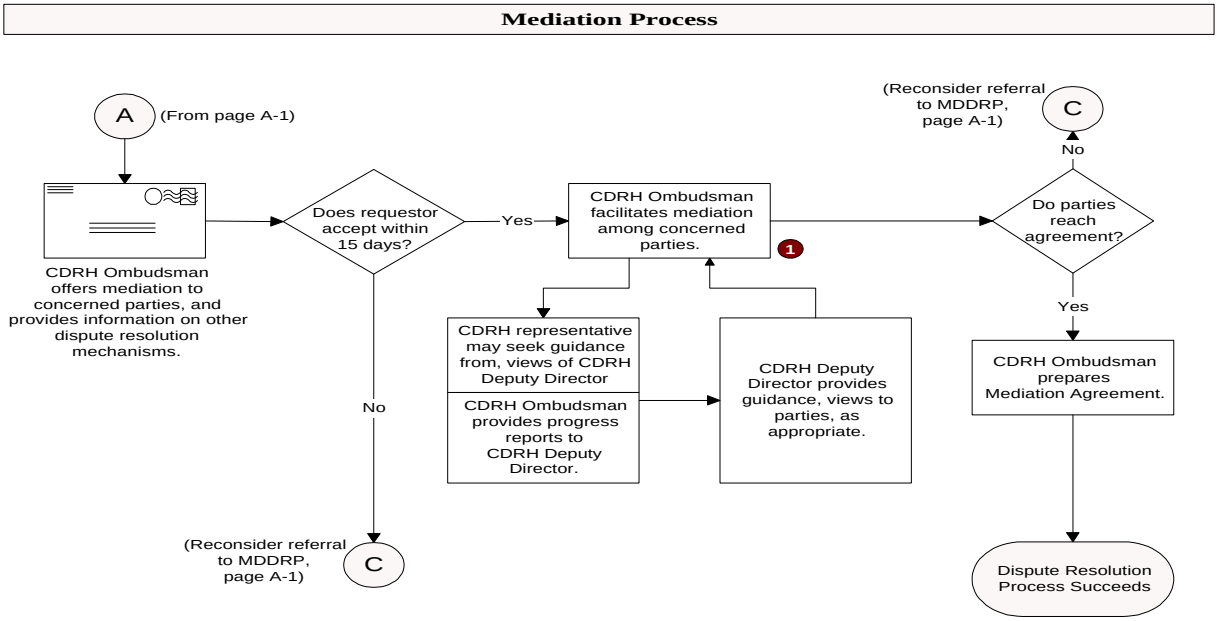
5. Medical Device Appeals and Complaints — A Handbook On Dispute Resolution.

6. Policy & Guidance — Handbook For FDA Advisory Committees.

APPENDIX A

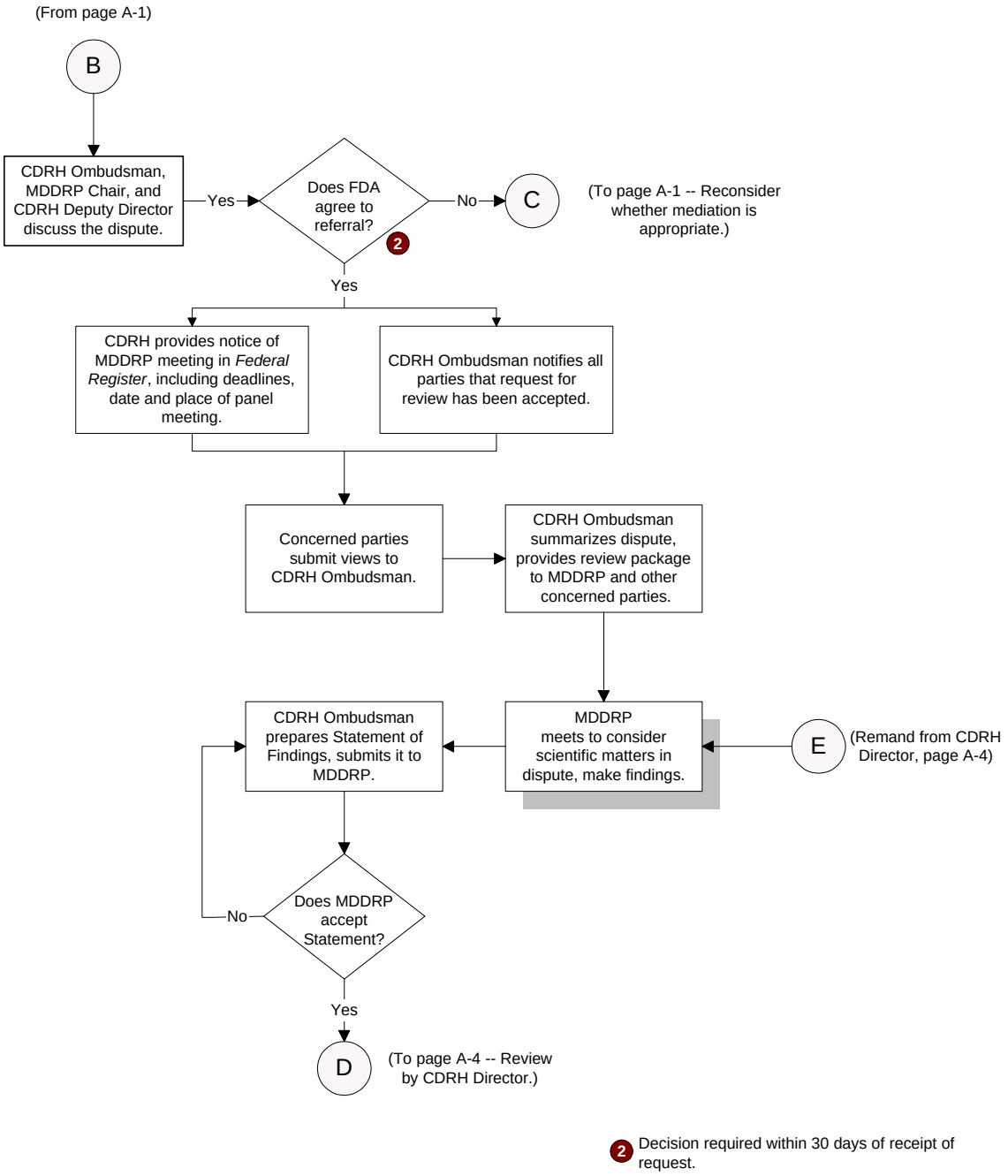
Overview of Medical Devices Dispute Resolution Panel Process



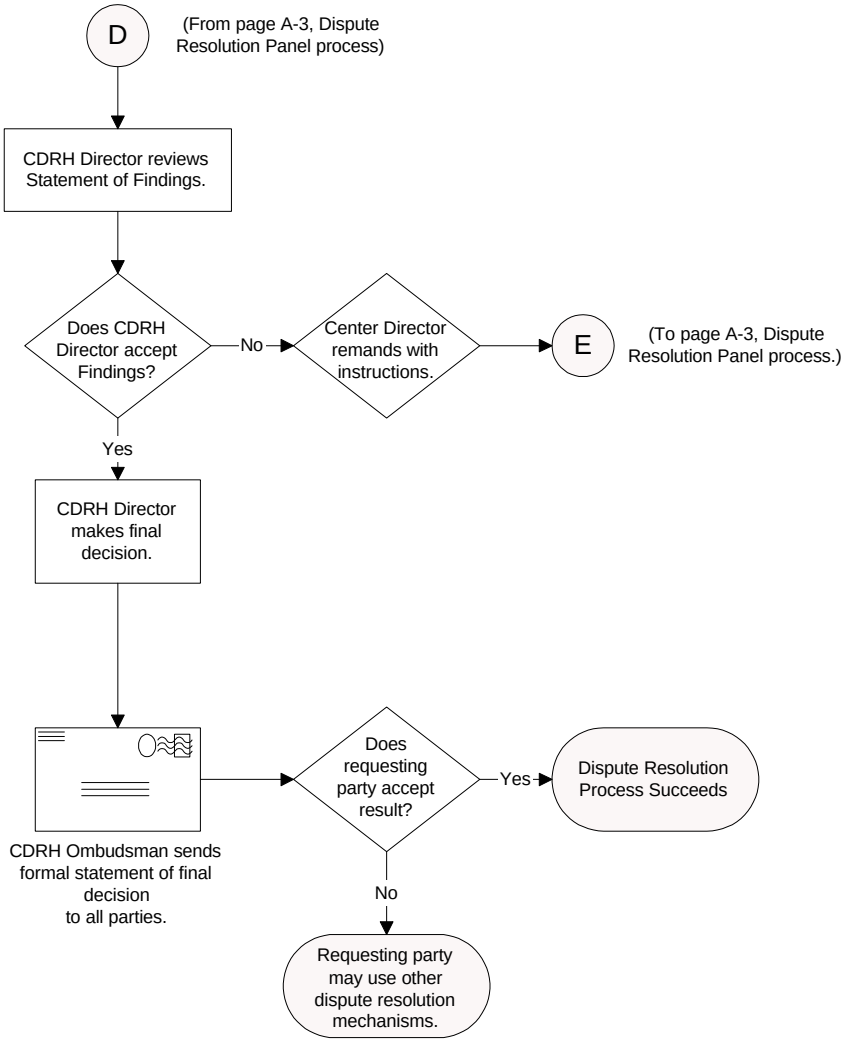


1 Typically, mediation should be concluded within 90 days.

MDDRP Accepts Request for Review, Conducts Review, Submits Statement of Findings



CDRH Center Director Considers Statement of Findings, Makes Final Decision



APPENDIX B

Medical Devices Dispute Resolution Panel Review Request Scenarios

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The following hypothetical cases illustrate how FDA expects to decide whether to grant a request for review of a scientific dispute by the Medical Devices Dispute Resolution Panel.

I. Cases That May Warrant Dispute Resolution Panel Review

Scenario 1:

CDRH finds a particular 510(k) submission to be not substantially equivalent (NSE) for scientific reasons. The applicant is unsuccessful in persuading ODE line management that the NSE decision is based on a misinterpretation of the underlying science by ODE review staff and requests review by the Dispute Resolution Panel.

Scenario 2:

The Orthopedic and Rehabilitation Devices Panel recommends against approval of a bone implant PMA. The Center concurs with the recommendation and issues a disapproval. The applicant lodges a protest against the Panel's action, alleging that: (1) the Panel erred in its conclusion that reasonable evidence of safety and effectiveness had not been presented; and (2) the Panel selectively considered the scientific information. The applicant requests independent review of the entire data set by the Dispute Resolution Panel.

Scenario 3:

A device company enters into a PDP with CDRH to prevent any misunderstanding with respect to the type and amount of clinical data needed in support of an eventual marketing application. Following completion of the studies, the applicant submits its data and is told that the data submitted does not meet the terms of the PDP. Efforts by the firm to appeal this judgment through the ODE management chain are unsuccessful. A request is made to have the Dispute Resolution Panel review the matter.

Scenario 4:

An ODE review division notifies an applicant that a PMA is "not fileable" because of incomplete scientific data. ODE management affirms this view. The applicant holds a differing view and demands that the Dispute Resolution Panel decide who is right.

Scenario 5:

A proposed order to require a five-year post-market surveillance study is drafted by FDA. The affected company does not agree to conduct the study, stating that no scientific purpose is served by collecting data beyond a three-year period. The company asks for review of the matter by the Dispute Resolution Panel.

Scenario 6:

With active involvement by the Center, FDA issues a Warning Letter indicating the possibility of enforcement action against a manufacturer if it continues to market a product as originally labeled despite the availability of new scientific information indicating the potential for a serious, previously unforeseen health hazard. Despite requests by the manufacturer to stay the enforcement action due to a difference of opinion over the science, FDA stands firm. The manufacturer requests Dispute Resolution Panel review.

II. Cases Not Warranting Dispute Resolution Panel Review

Scenario 1:

A PMA applicant is told by the lead CDRH reviewer that an additional clinical study is needed in order to fully evaluate the submission. The applicant contests the additional information request on the grounds that it constitutes scientific excess and differential treatment compared to the data requirements imposed on competitors. The applicant requests review for Dispute Resolution Panel review.

Primary reason for declining Dispute Resolution Panel review: Applicant has not pursued supervisory review as a matter of first course.

Scenario 2:

A "for cause" inspection of a device manufacturer is conducted by FDA bioresearch monitoring investigators as a result of information provided by a competitor firm. The inspection turns up evidence of possible data fraud associated with an approved market application. The manufacturer wishes to defend the integrity of the data through independent review and validation, and asks for review of the matter by the Dispute Resolution Panel.

Primary reason: Request relates to an allegation of criminal misconduct, a matter that is outside the purview of the Dispute Resolution Panel.

Scenario 3:

A spate of MDR reports is received on a widely-used medical device that indicates a probable connection between use of the device and increased patient mortality. The scientific analysis performed by CDRH results in the issuance of a nationwide Safety Alert, the basis for which is disputed by the product manufacturer. The company asks FDA to withdraw the Safety Alert until the matter can be brought before the Dispute Resolution Panel.

Primary reason: The filing of a request for review of a matter by the Dispute Resolution Panel will not affect, delay, stay, or preclude any ongoing or future seizure, recall, suspension of marketing authority, or other regulatory action which FDA deems necessary to protect the public health.

Scenario 4:

An IDE applicant requests and obtains a pre-submission conference with ODE division staff and a subsequent meeting with Office-level officials in an effort to reach agreement over the PMA data requirements for a particular investigational device. The two sides find they are worlds apart, leaving the applicant to believe that an impartial review of the matter is the only means by which to settle the disagreement.

Primary reason: No formal FDA decision or action has been taken. Concerns could instead be directed to the CDRH Director.

Scenario 5:

A company is informed by an FDA district office that it is unlawfully marketing a medical device and that distribution should be halted pending submission to and clearance by FDA of a 510(k). The firm challenges the decision and asserts that the product does not meet the legal definition of a medical device. In support of its position, the firm cites a variety of publications, which FDA finds unpersuasive. Efforts by the CDRH Ombudsman to mediate the dispute are unsuccessful, leading the firm to request a review by the Dispute Resolution Panel.

Primary reason: The issue is not a scientific issue per se; it involves a question of regulatory jurisdiction requiring a legal/regulatory determination that is outside the scope of the Dispute Resolution Panel.

Scenario 6:

A company seeking to market a drug-device combination product is told by FDA that the product must be regulated as a drug. The company disagrees and submits scientific evidence purporting to

show that the device component is the primary mechanism of action. After a review of the scientific evidence proffered by the firm, FDA reaffirmed its position. The manufacturer asks for an independent review of the evidence by the Dispute Resolution Panel.

Primary reason: FDA's Chief Mediator and Ombudsman has exclusive authority to resolve product jurisdiction issues. This is outside the purview of the Dispute Resolution Panel.

Scenario 7:

A competitor of a PMA holder challenges the scientific basis of FDA's approval, claiming that new, post-approval information has come to light calling the approval into question and implying new safety concerns. The competitor asks for independent review by the Panel.

Primary reason: Only a "sponsor, applicant, or manufacturer" can request a review of a matter by the Dispute Resolution Panel. The competitor does not have standing and must use one of the alternative dispute resolution processes provided by FDA.

APPENDIX C

Sample Statement of Findings Memorandum

MEMORANDUM

[Date of memo]

To: CDRH DIRECTOR

Through: CDRH Deputy Director for Science _____

From: CDRH Ombudsman

Subject: Medical Devices Dispute Resolution Panel Statement of Findings
[Identify case by name of party.]

ISSUE

(Provide a concise summary of the FDA decision or action being disputed, the effective date of the decision/action, the identity of the party or parties contesting the decision/action, the date of review by the Medical Devices Dispute Resolution Panel, and a brief overview of the Panel findings.)

PRELIMINARY ACTIONS

(Describe all pre-Panel efforts to resolve the dispute, including supervisory re-consideration, formal petitions for re-consideration, mediation by the CDRH Ombudsman, etc. Also provide the date the matter underwent preliminary review by the CDRH Ombudsman and Dispute Resolution Panel Chair, the reasons for proceeding with Dispute Resolution Panel review of the matter, and the composition of the Panel that reviewed the matter, including any waivers that may have been granted to individual Panel members.)

KEY FACTS CONSIDERED

(Give a synopsis of the arguments, written and oral, and substantiating data and information presented by the requesting party or authorized representative, in addition to any such information offered by other interested and affected parties, prior to and during the meeting of the Dispute Resolution Panel. Information outside the administrative record should be highlighted and the basis for permitting its consideration. This section should also include relevant citations from the FD&C Act, FDA regulations and FDA policies that bear on the original CDRH decision/action and the subsequent dispute. Also provide any public health impacts asserted by the disputing parties in relation to the contested decision/action or purportedly could result if the decision/action is either upheld or reversed.)

Sample Statement of Findings Memorandum (Continued)

STATEMENT OF FINDINGS

(Provide an overview of the Panel's deliberations, including areas of agreement and disagreement among the members, key concerns, the Panel's overall conclusions and recommendations, and the final vote if one was taken. Include minority views.)

CONCURRENCE

We, the members of the Medical Devices Dispute Resolution Panel, having met on (insert date) for the purpose of reviewing (restate the name of the case and case number), do hereby attest that the statements and facts contained herein are accurate and endorse the Statement of Findings as presented.

Panel Chair	Member	Member
Member	Member	Member
	CDRH Ombudsman	

CENTER DIRECTOR DECISION

☐ I concur with the Panel recommendation(s).

☐ I concur with the Panel recommendation(s) with the following exception(s):

☐ I do not concur with the Panel recommendation(s) and direct that the following actions be taken:

Elizabeth D. Jacobson, Ph.D. Date
Acting Director, Center for Devices and Radiological Health

APPENDIX D

Extracts from the Food, Drug, and Cosmetic Act

21 U.S.C. § 351 *et seq.*

These extracts highlight the statutory role and responsibilities assigned by FDA to the Medical Devices Dispute Resolution Panel. The official version, as provided by Title 21 of the United States Code, should be consulted for the full text of these provisions.

§ 514(b)(5) — Performance Standards — Report and recommendation by advisory committee.

(A) The Secretary —

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments ...,

to an advisory committee of experts ... for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. .... The advisory committee shall, within sixty days of the referral ... submit ... a report and recommendation respecting such regulation .... A copy of such report shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as non-voting members a representative of consumer interests and a representative of interests of the device manufacturing industry. ....

§ 515(g) — Premarket Approval (PMA and PDP) — Review.

(1) Upon petition for review of —

> (A) an order ... approving or denying approval of an application or an order ... withdrawing approval of an application, or
>
> (B) an order ... revoking an approved protocol, ... declaring that an approved protocol has not been completed, or ... revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review ... has been submitted under paragraph (2), hold a hearing ... on the order. .... Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2) —

> (A) Upon petition for review of —
>
> > (i) an order ... approving or denying approval of an application or an order ... withdrawing approval of an application, or
> >
> > (ii) an order ... revoking an approved protocol, ... declaring that an approved protocol has not been completed, or ... revoking the approval of a device,
>
> the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.
>
> (B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title [§ 513 of the FD&C Act]) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. .... The Secretary shall designate the chairman of an advisory committee from its members. The Secretary ... shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

> (C) The Secretary shall make public the report and recommendation made by an advisory committee ... and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

§ 522(b) — Postmarket Surveillance — Surveillance Approval. (This provision was added by § 212 of the Food and Drug Administration Modernization Act of 1997.)

Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required ... to conduct such surveillance, submit ... a plan for the required surveillance. .... The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination ... that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562.

§ 562 — Dispute Resolution. (This provision was added by § 404 of the Food and Drug Administration Modernization Act of 1997.)

If, regarding an obligation concerning ... devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate ... advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997.